EXHIBIT C

CONSUMER PRODUCT TESTING COMPANY
cptclabs.com

FINAL REPORT

CLIENT: Denittis Osefchen Prince, P.C.
5 Greentree Centre – Ste 410
525 Route 73 N.
Marlton, NJ 08057

ATTENTION: Stephen DeNittis

TEST: Clinical Evaluation of Sunscreen Efficacy with the Sun Protection Factor Assay, Water Resistant Assay and Calculation of the Label SPF - FDA Final Rule Water Resistant (80 minute) Method
Protocol: CP-07.72

TEST MATERIAL: Banana Boat SPF 50 lotion, Lot#: 153205665

STUDY NUMBER: S18-7262

M Caswell 20Dec2018
Approved By:
Michael Caswell, Ph.D., CCRC, CCRA
Vice President, Clinical Evaluations

Report Date: December 20, 2018

CONSUMER PRODUCT TESTING COMPANY
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FDA Registration# 1000151293
DEA Registration# RC0199744 Schedule I-V
US EPA/NJ DEP Registration# NJ0982726648
ISO/IEC 17025:2005 Accredited

QUALITY ASSURANCE UNIT STATEMENT

Study Number: S18-7262

The Consumer Product Testing Company, Incorporated (CPTC) Quality Assurance Unit (QAU) is responsible for auditing the conduct, content and reporting of all clinical trials that are conducted at CPTC.

This trial has been conducted in accordance with the Declaration of Helsinki, the ICH Guideline E6 for *Good Clinical Practice*, the requirements of 21 CFR Parts 50 and 56, other applicable laws and regulations, CPTC Standard Operating Procedures, and the approved protocol.

The CPTC QAU has reviewed all data, records, and documents relating to this trial and also this Final Report. The following QAU representative signature certifies that all data, records, and documents relating to this trial and also this Final Report have been reviewed and are deemed to be acceptable, and that the trial conforms to all of the requirements as indicated above.

All records and documents pertaining to the conduct of this trial shall be retained in the CPTC archives for a minimum of ten (10) years. At any time prior to the completion of the tenth archival year, a Sponsor may submit a written request to the CPTC QAU to obtain custody of trial records once the CPTC archive period has been completed. This transfer shall be performed at the Sponsor's expense. In the absence of a written request, trial-related records shall be destroyed at the end of the CPTC archive period with no further notice in a manner that renders them useless.

William Cavaliere
Quality Assurance Representative

12/21/2018
Date

Background Information

An over-the-counter sunscreen product in a form suitable for topical administration is generally recognized as safe and effective if it meets the requirements found in the Final Rule issued by the Food and Drug Administration (reference 1). This trial was designed to evaluate the Sun Protection Factor (SPF) of a test material as a sunscreen product after an 80 minute water immersion procedure, in accordance with the requirements delineated in this methodology.

Trial Objective

The primary objective of this trial was to determine the water resistant (80 minutes) SPF of a test material using the methodology described in the Final Rule (SPF) Test Method (reference 1).

Trial Schedule

Initiation Date:	Completion Date:
November 14, 2018	December 20, 2018

Test Material Banana Boat SPF 50 lotion, Lot#: 153205665
(Expected SPF= 15)

Standard

A control standard, 7% Padimate O/3% Oxybenzone was run concurrently with the test material to verify proper and consistent performance of test equipment and procedures. The control standard has a mean SPF of 16.3 with a standard deviation of 3.43.

Storage

Test materials were stored at ambient temperature and humidity in the container in which they were received by CPTC.

The control standard was stored in a refrigerator at 4°C to 8°C and ambient humidity. The control standard was allowed to warm to room temperature prior to use.

Disposition

At the conclusion of the trial, all remaining test material is retained by CPTC for 6 months and then discarded in accordance with local, state and federal laws and regulations unless the Sponsor has arranged for a different disposition in writing.

The control standard was returned to the refrigerator and will be used in additional trials until the entire control standard has been used or the expiration date has been reached.

Selection and Withdrawal of Subjects

Number of Subjects

A minimum of 10 valid results are required for each panel. An initial assessment of 5 subjects may be conducted to evaluate a preliminary SPF value. An additional 5 subjects may be added to the initial 5 subjects to form a complete panel of 10 subjects. A maximum of 3 individual results may be excluded from the calculation of the mean SPF but each one must be justified in accordance with the "Rejection of Data" section, which appears later in this Report.

Subjects who meet all of the inclusion criteria and none of the exclusion criteria qualified for the trial.

Inclusion Criteria

1. Subjects who had a Fitzpatrick skin phototype I, II or III (described below), or an ITA° value of larger than 28° by colorimetric method:

Skin Type	Sunburn and Tanning History
I	Always burn easily; never tans
II	Always burns easily; tans minimally
III	Burns moderately; tans gradually

2. Subjects were aged 18 to 65 years, inclusive.

3. Subjects were considered suitable by a healthcare professional prior to their trial initiation.

4. Subjects agreed to cover the test site to the sun for 4 weeks prior to their trial initiation.

5. Subjects completed a Medical History Form and understood and executed an ICF.

6. Subjects were considered dependable and capable of understanding and following directions.

Exclusion Criteria

1. Subjects who had a history of abnormal response to sunlight, such as lupus erythematosus or skin cancer.

2. Subjects who had a sunburn, suntan, uneven skin color or visible disease that would interfere with evaluation of test results.

3. Subjects who had nevi, blemishes or moles, which, in the opinion of the PI, would interfere with the trial results. Subjects with excessive hair on the test site unless they agreed to its being shaved.

4. Subjects who were in ill health or taking medications other than birth control, which could influence the purpose, integrity or outcome of the trial.

5. Subjects who use a tanning bed or overexpose themselves to sunlight on the test site.

6. Female subjects who were pregnant, planning to become pregnant or nursing during the course of the trial.

7. Subjects who had participated in testing procedures that precludes a sufficient area being clear of all previous skin tanning.

8. Subjects who had experimented on the test site within the previous 2 months.

Methodology

Instrumentation

Single-port or multi-port xenon arc solar simulators (150 W or 300 W) equipped with WG320 and UG11 filters were used as the source of full spectrum UV radiation (Solar Light Company, Philadelphia, PA). This instrument, described in detail (reference 2), provided a continuous spectral output in the UVB range (290 nm – 320 nm), the UVAII range (320 nm – 340 nm) and the UVAI range (340 nm – 400 nm) that is similar to sunlight.

The performance of the solar simulators depends on their spectral output. Therefore, the solar simulator spectral output specification is less than 1500 W/m^2 for the total irradiance range of 250 nm to 1400 nm and a beam uniformity of 20% (reference 1). The maximal irradiance was confirmed to avoid excessive heat feeling during the SPF test. Irradiance for UVAII and UVAI equaled or exceeded 20% and 60%, respectively, of the full spectrum UV radiation.

The erythemal effectiveness of each wavelength band is expressed as a percentage of the total erythemal effectiveness from less than 290 nm to 400 nm, or as the Percent Erythemal Contribution (%EC). The following table indicates the %EC acceptable output limits for the solar simulators.

	% Erythemal Contribution	
Wavelength Range (nm)	Lower Limit	Upper Limit
<290		<0.1
290-300	1.0	8.0
290-310	49.0	65.0
290-320	85.0	90.0
290-330	91.5	95.5
290-340	94.0	97.0
290-400	99.9	100.0

Solar simulators were provided an appropriate warm-up period, after which, they were expected to have no significant time-related fluctuations in radiation emissions. Each solar simulator had good beam uniformity in the exposure plane. To ensure that the solar simulators deliver the appropriate spectrum of UV radiation, their spectral output is measured biannually with an accurately calibrated spectroradiometer.

The lamp output was measured after warm-up with a UV intensity meter (Model PMA2100, Solar Light Company, Philadelphia, PA) equipped with the appropriate detector before and after the test period. The delivered dose to each subsite was within 10% of the expected dose. In addition, if a significant physical component of the solar simulator was changed, CPTC measured the spectral output.

Whirlpool

Water jets of the fresh water indoor whirlpool bath (23°C – 32°C) were adjusted to simulate moderate activity in the water.

Ambient temperature and humidity of the pool area was recorded twice daily, morning and evening.

Determination of MED of Unprotected Skin

Methodology

Prior to the test material phase, the MEDu of each subject was determined by a progressive sequence of timed UV radiation exposures, each of which was graduated incrementally by 25% over that of the previous exposure. The sites were evaluated for erythema according to the MED Scoring Scale (See below). The MEDu is the smallest UV dose that produces perceptible redness of the skin (erythema) with clearly defined borders at 16 to 24 hours after UV exposure (Score = 1 on the MED Scoring Scale). The MEDu test site was in close proximity to the MEDp test sites.

MED Scoring Scale

Score	Description
0	No reaction
0.5	Equivocal reaction, barely perceptible erythema with no clearly defined border
1	Mild but definite erythema with clearly defined borders
2	Moderate clearly defined erythema
3	Strong erythema, edema
4	Bulla or vesiculation

Determination of MED of Protected Skin

Test Material Application

A sufficient number of 40 cm^2 test sites were outlined with a surgical marking pen on the subject's back between the scapulae and the beltline, lateral to the midline. These sites were designated for each test material and a control standard, with an adjacent site designated for a concurrent MED determination of unprotected skin. The position of the test sites was randomly distributed on the back over the entire group of subjects.

Test material preparation, test material application, UV exposures and MED assessments were performed in ambient conditions (18-26°C) according to CPTC internal SOPs. The test material was applied to the subject while in the testing position (either upright or prone).

A portion of test material or control standard was applied to the appropriate 40 cm^2 test site and spread evenly over the site using a fingercot, providing a test material film of approximately 2 mg/cm^2. The actual weight applied was recorded on the CRF. If two or more sunscreen test materials were being evaluated in the same trial, the test materials and control standard were applied to sites that had been randomized by test material.

There was a minimum distance of 1 cm between the borders of adjacent test material application sites, and the test sites were randomly distributed on the subject's back and throughout the panel. The area of each subsite was at least 0.5 cm^2 and the distance between borders of each of the exposure subsites was at least 0.8 cm.

At least 15 minutes after test material or control standard application, the test site was divided into 6 subsites, which were used for a progressive sequence of timed UV radiation exposures. The area of each subsite was at least 0.5 cm^2 and the minimum distance between subsite borders was 0.8 cm.

UV Exposures

UV exposures were selected for each subsite in treated areas based upon the previously determined MED of the unprotected skin and the Sponsor-supplied expected SPF of the test material or the control standard's SPF of 16.3.

For test materials with a Sponsor-supplied expected SPF less than 8, the exposures were the previously determined MED times:

0.64X, 0.80X, 1.00X, 1.25X & 1.56X

where X = Sponsor-supplied expected SPF.

For test materials with a Sponsor-supplied expected SPF between 8 and 15, the exposures were the previously determined MED times:

0.69X, 0.83X, 1.00X, 1.20X & 1.44X

where X = Sponsor-supplied expected SPF.

For test materials with a Sponsor-supplied expected SPF greater than 15, the exposures were the previously determined MED times:

0.76X, 0.87X, 1.00X, 1.15X & 1.32X

where X = Sponsor-supplied expected SPF.

Subjects were in the same position (either seated upright or prone) during test material application, irradiation, and MED assessments. After irradiation was completed, the control standard and test materials may have been gently removed using a cotton pad with a mild lotion such as makeup remover or other similar product. The minimal erythemal dose for unprotected skin (MEDu), that for protected skin (tpMEDp), and that for the control standard (ssMEDp) were determined on the same day.

Water Resistant (80 minutes) Evaluation

Additional SPF irradiations were made after timed intervals of immersion in a fresh water indoor whirlpool bath (23°C – 32°C). SPF irradiations were made after 80 minutes of water immersion (four 20 minute immersion intervals, each followed by a period of at least 15 minutes to rest and air dry). The test sites were allowed to air dry without toweling.

The "Water Resistant (80 minutes)" SPF value was calculated as described in the statistical methods, which appears later in this Report.

Evaluation

After irradiation was completed, all immediate responses were recorded on CRFs. These might have included several types of typical responses such as immediate reddening, immediate darkening or tanning, and an immediate generalized heat response. After immediate responses were noted, each subject was required to shield the exposed test sites from further UV radiation until evaluation of the test subsites the following day.

So the person who evaluates the MED response did not know which test material or control standard was applied to which site or what doses of UV radiation were administered, that person was not the same person who applied the test material or control standard or administered the UV radiation.

Each test subsite was evaluated 16 to 24 hours after exposure to determine an MED. The MED is the quantity of erythema-effective energy (expressed in milliJoules per square centimeter) required to produce the first perceptible redness reaction with clearly defined borders (Score = 1 on the MED Scoring Scale). Evaluations were performed in sufficient illumination (tungsten or warm white fluorescent lighting) with at least 450 lux. For the evaluation, the subject was in the same position as when the subsites were irradiated.

Statistical Methods

Rejection of Data

Test data from a subject was deemed to be invalid and rejected for any of the following reasons:

- If the exposure series failed to elicit an MED response on either the treated or unprotected sites; or
- If the responses on the treated sites were randomly absent (which indicated the test material (or control standard) was not spread evenly); or
- If the subject was non-compliant (*e.g.,* subject withdrew from the test due to illness or work conflicts, subject did not shield the exposed testing sites from further UV radiation until the MED is read, *etc.*).

SPF Calculation for Test Material on a Subject (SPFi)

The SPF is defined as the ratio of the energy of exposure to full spectrum UV, 290 nm – 400 nm, to produce erythema in human skin in the presence of a test material (or control standard), applied at 2 mg/cm^2, to that in its absence and is calculated as follows:

$$SPFi = \frac{\text{MED Protected Skin}}{\text{MED Unprotected Skin}}$$

SPF Calculation for a Test Material on the Panel

The SPF of the test material is defined as the arithmetic mean of the individual (SPFi) values obtained from the total number (n) of subjects used, expressed to one (1) decimal point:

$$SPF = (\sum SPFi) / n$$

Its standard deviation, s, is:

$$s = \sqrt{[(\sum SPFi^2) - ((\sum SPFi)^2 / n)) / (n-1)]}$$

The standard error (SE) is:

$$SE = s / \sqrt{n}$$

The SPF for the test material is the largest whole-number less than *x*-A, where *x* is the mean SPF value of all valid data.

Calculation of A: $A = \frac{(t)(s)}{\sqrt{n}}$

Where n = number of subjects,
t = upper 5% point from the t distribution with n-1 degrees of freedom and
s = standard deviation.

For the SPF determination of the test material to be considered valid, the SPF value of the control standard must fall within the standard deviation range of the expected SPF (i.e., 16.3±3.43).

SPF Calculation for a Test Material for the Water Resistant (80 minutes) Panel

The test materials may be labeled "Water Resistant (80 minutes)" using the SPF value determined after the water immersion process.

Amendments

There were no amendments.

Deviations

For Subject # 3, the MED evaluation for the pre-immersion test material treated test site occurred 6 minutes after the allowed time of 16-24 hours, as described in the protocol.

Subject # 8, Immersion II, was 1 minute longer than the 20-minute immersion time described in the protocol.

Subject # 12, Immersion II and III, were both 1 minute longer than the 20-minute immersion time described in the protocol.

The PI judged these deviations to have no impact on clinical trial results.

Adverse Events

There were no adverse events.

Test Results

Of the 12 subjects who enrolled into the trial, 12 qualified, and 12 completed the trial.

Subject #s 1 and 7 were not included in the final results due to erythema in all subsites of the test material treated area. Overall results were based on valid data from 10 subjects.

SPF calculations for each subject are shown in Table 1.

Conclusion

Under the conditions of this trial, the average static Sun Protection Factor (SPF) of test material Banana Boat SPF 50 lotion, Lot#: 153205665 is calculated to be 10.4 with a SPF Label of 9.

Under the conditions of this trial, the average water resistant (80 minute) SPF of test material Banana Boat SPF 50 lotion, Lot#: 153205665 is calculated to be 9.3 with a SPF label of 7.

References

1. Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use. Federal Register 2011:76;35620-35665.

2. Berger DS. Specification and design of solar ultraviolet simulators. *J Invest Dermatol* 1969;53:192-199.

Table 1

Individual SPF Values

Subject Information #	Initials	ID #	Photo type	Age	Gender	MED (mJ/cm2) Untreated	Control Standard	Test Material PRE	Test Material POST	Banana Boat SPF 50 lotion, Lot#: 153205665 Control Standard	Static PRE	WR (80 min) POST
1	M-R	14243	II	48	M	21.6*	465.6*	<187.7*	<187.7*	21.6*	<8.7*	<8.7*
2	NJV	34296	III	53	M	43.7	819.2	455.1	455.1	18.7	10.4	10.4
3	C-R	7420	II	52	M	15.2	356.0	190.2	190.2	23.4	12.5	12.5
4	GNB	82623	III	57	F	35.4	461.3	339.4	196.6	13.0	9.6	5.6
5	R-D	83972	III	37	F	35.4	501.9	353.8	294.7	14.2	10.0	8.3
6	MEP	82274	II	62	F	19.0	356.0	228.1	273.8	18.7	12.0	14.4
7	EJR	88217	I	23	M	9.7*	247.6*	126.7*	<87.9*	25.5*	13.1*	<9.1*
8	P-L	9304	II	59	F	21.8	283.5	208.8	145.0	13.0	9.6	6.7
9	JAG	82103	III	50	M	24.5	399.2	244.9	204.0	16.3	10.0	8.3
10	MCM	85280	II	27	F	27.2	355.5	261.3	313.5	13.1	9.6	11.5
11	NMZ	84281	III	21	F	31.6	448.0	263.4	219.7	14.2	8.3	7.0
12	Y-C	84685	II	45	F	24.5	347.1	293.8	204.1	14.2	12.0	8.3
Average SPF										15.9	10.4	9.3
Number of Subjects (n)										10	10	10
Standard Deviation										3.44	1.34	2.83
Standard Error										1.09	0.42	0.89
t (one-tail)										1.833	1.833	1.833
A										1.99	0.78	1.64
SPF Label Value										13	9	7

<=Data invalid, erythema in all subsites.
*=Data not included in calculations.
Note: Subjects 1-2 were run at SPF 15.
Note: Subjects 3-12 were run at SPF 10.